Co-Site Visit Report

Audit Date : **00/00/2002** **Group :** ANYG **Audit Category :** Combined **Audit Type :** Routine audit
Institution Code : **MM000** **Name :** **Some Regional Site CCOP, Big City, XX zip00**
Main Member / CCOP Code : MM000 ***Name :*** AA Hospital
Audit Location : Some Regional Site CCOP, Big City, XX zip00

Number of Cases Audited : 20 **Principal Investigator :** Anonymous Who, M.D. **Number of Protocols Reviewed :** 6

Co-Site Auditor Information

Name	Title	Affiliation
John Doe, Jr., Pharm.D.		Theradex

Audit Outcome Summary

Component	Assessment
IRB and Informed Consent Content Assessment	Acceptable
Accountability of Investigational Agents and Pharmacy Operations Assessment	Acceptable
Review of Patient Case Records Assessment	Acceptable needs follow-up

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I. IRB and Informed Consent Content Review:

A. IRB Review	Finding	Comments
1. Were each of the selected protocols available at the site?	Yes	
2. Was the most up-to-date version of the protocol available?	Yes	
3. Did the auditors review IRB documentation at the site or off-site?	On-site	The IRB documentation was reviewed on-site.
4. Were the protocols reviewed for initial IRB approval?	Yes	
5. Were all annual re-approvals reviewed by IRB?	Yes	
6. Were all amendments reviewed and approved by the IRB?	Yes	
7. Did the auditors follow CTMB guidelines?	Yes	
8. Did the auditors conduct an adequate review?	Yes	

B. Informed Consent Content (ICC) Review:		
1. Were locally used informed consents reviewed?	Yes	
2. Were local informed consent documents reviewed onsite or offsite?	Off-site	Three local informed consent forms were chosen to be reviewed off-site prior to the visit.
3. Did the auditors conduct an adequate review?	Yes	

C. IRB and Informed Consent Content Assessment : Acceptable

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II. Accountability of Investigational Agents and Pharmacy Operations Review:

	Finding	Comments
1. Were INDs in use during the period covered by this audit?	Yes	
2. Was the pharmacy visited?	Yes	The Big City Central Medical Center Pharmacy was visited. The pharmacies of the other affiliated institutions were not visited because of the location.
3. Are NCI DARFs in routine use?	Yes	
4. Were NCI DARFs reviewed on-site or off-site?	On-site	NCI DARFs were reviewed only for Big City Central Medical Center. The NCI DARFs did not always contain patient identification numbers as well as patient initials.
5. Was the pharmacy inspected according to CTMB guidelines?	Yes	
6. Was there adequate security?	Yes	
7. Were affiliate NCI DARFs reviewed?	No	No other affiliate pharmacies were visited.
8. Did the auditors conduct an adequate review?	Yes	

Accountability of Investigational Agents and Pharmacy Operations Assessment : Acceptable

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III. Patient Case Review:

	Finding	Comments
1. Were informed consent documents reviewed?	Yes	
2. Were any major informed consent problems noted?	No	The investigator had not signed two patient consents prior to sending to ANYG, however the auditor found that the consents were signed by the investigator and dated afterwards.
3. Was each audited case reviewed for eligibility?	Yes	
4. Were any major eligibility problems noted?	No	
5. Were any major treatment deviations noted?	Yes	Patient zzzzz on zzzzz developed ANC < 1.5. The patient was treated while the protocol necessitated withholding treatment.
6. Were any major response/disease outcome discrepancies noted?	No	
7. Were any major toxicity problems noted?	No	Grade 1 taste disturbance and neurosensory events were located in the source documents but were not reported for Patient zzzzz on zzzzz. The grade 4 neutropenia reported for this patient was found to be incorrectly reported. AdEERs report for grade 2 mouth dryness was required for Patient zzzzzz on zzzzz because this event was not listed on the agent specific AE log for xxxxxxxxxx at the time the event occurred. The AdEERs was not submitted prior to the visit.
8. Were any major data quality problems identified?	No	
9. Were the materials available for the audit adequate?	Yes	Patient zzzzz on zzzzz was noted to have "severe" nausea, however the toxicity form indicates only grade 1 nausea. Patient zzzzz on zzzzz experienced severe constipation according to documentation, however this was not found to be recorded on the toxicity form.

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10. Did the auditors conduct an adequate review? Yes

Review of Patient Case Records Assessment : Acceptable needs follow-up

Exit Interview

1. Was the exit interview attended by the PI? : Yes

2. Were the preliminary audit findings stated and discussed? : Yes

3. Were recommendations made? If "Yes", explain below. : No

4. Did the auditors conduct an adequate exit interview? : Yes

Exit Interview Comments :

1. The auditors recommended that there be improvement in documentation of adequate contraception and pregnancy status.

2. All informed consent forms should be signed and dated by the investigator at the time the patient signs the consent.

3. The auditors recommended that there be more physician involvement in grading of toxicities to decrease the discrepancies in the documentation.

4. The documentation of administration of oral medications could be improved. The auditors suggested that documentation of this include a short statement to indicate whether the patient received all oral medications.

5. Tumor measurements were discussed and the auditors recommend that the investigators be more involved in the measurements of disease and follow their own patients for more consistency.

6. The auditors recommend that all of the affilitate institutions be reviewed for pharmacy and IRB compliance by the main institution on a regular basis.

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7. The protocol status that zzzzz should be administered according to the ASCO guidelines. This was not always done.

General Comments:

1. Was the audit conducted according to CTMB Guidelines? : Yes

Overall Comments and Recommendations : The major deviations were discussed with the staff during the exit interview. The auditors indicated that the research staff was very helpful in facilitating the visit and they had seen much improvement since the last audit. The chart organization was very helpful. The auditors stated that the cancer control protocols were very well organized and complete.

Some S Secretary	00/00/2002	Anonymous X Who, M.D.	00/00/2002
Prepared By	**Date**	**Approved By**	**Date**